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Diego, CA 92131 (US). KOVACH, Eric [US/US]; 3107
Quebrada Circle, Carlsbad, CA 92009 (US).

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(74) Agent: SPANGLER, Jonathan, D.; 10065 Old Grove
Road, San Diego, CA 92131 (US).

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(71) Applicant (for all designated States except US): NUVA-
SIVE, INC. [US/US]; 10065 Old Grove Road, San Diego,
CA 92131 (US).

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(72) Inventors; and

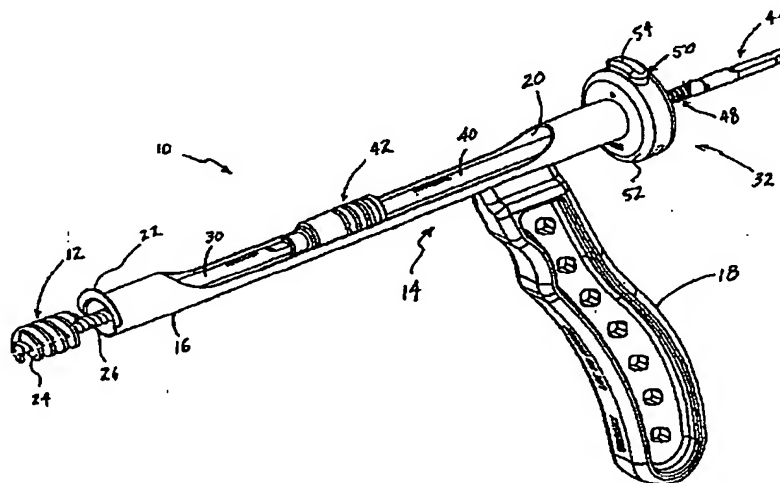
(75) Inventors/Applicants (for US only): SUTTERLIN,
Chester, M., D. [US/US]; Spinal Health Centers, 7120
NW 11th Place, Gainesville, FL 32605 (US). BLAIN, Ja-
son [US/US]; 11662 Corte Gueka, San Diego, CA 92128
(US). CURRAN, Matthew [US/US]; 3218 Rancho Quar-
tillo, 10983 Caminito Arcada, San Diego, CA 92131 (US).
WOOLLEY, Troy [US/US]; 10983 Caminito Arcada, San

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(54) Title: SYSTEMS AND METHODS FOR REMOVING BODY TISSUE



(57) Abstract: Devices and methods for removing body tissue involving the use of a brush member (12) having a plurality of bristle members defining a capacity for carrying body tissue. The brush member (12) is capable of being manipulated within said body to thereby receive body tissue within said brush member.

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SYSTEM AND METHOD FOR REMOVING BODY TISSUE**CROSS-REFERENCE TO RELATED APPLICATION**

This application claims the benefit of the filing date under 35 USC 119(e)
5 of U.S. Provisional Application entitled "Discectomy Brush," Serial No.
60/322,489, filed Sept. 10, 2001, the entire contents of which are hereby expressly
incorporated by reference into this disclosure as if set forth fully herein.

BACKGROUND OF THE INVENTION

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I. Field of the Invention

This invention relates to devices and methods for removing body tissue.
More particularly, the present invention relates to devices and methods for
removing body tissue involving the use of a brush or brush-like element capable
15 of collecting, carrying, or otherwise receiving body tissue for removal.

II. Discussion of the Prior Art

A large variety of pathologies affecting many different body tissues
indicate the use of tissue ablation (i.e., removal or destruction of a tissue).
20 Examples of such procedures include knee meniscectomy, knee synovectomy,
chondromalacia and tears, loose body debridement, lateral retinacular release,
plica removal, ligament and tendon release, contouring and sculpting of articular

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surfaces, debridement of inflamed synovial tissue, capsulectomy in the knee, complete or partial resection of internal organs, tumors and lesions.

Tissue ablation can be accomplished using many different ways, the two
5 main categories consisting of mechanical and energy focusing means.
Mechanical tools are used to cut away the targeted tissue. Thermal energy has
also been used which heats the targeted tissue until the cells die. Lasers,
radiofrequency waves, microwaves, ultrasound, and cryotherapy have all been
used in thermal techniques. In a related technique, an electrical current is used to
10 excite a fluid, creating a plasma layer. The highly energized plasma layer then
incrementally disintegrates layers of the tissue.

The existing techniques suffer from a host of disadvantages. Typically,
mechanical devices are small and remove tissue in very small increments. As a
15 result, when large amounts of tissue must be removed the excision time may be
exorbitant. The energy focusing techniques, in addition to suffering from the time
disadvantage of the mechanical devices, are further limited. The energy levels
applied to the tissue must be conservatively regulated to avoid damaging tissue
beyond the targeted tissue.

20

One procedure, in particular, that is hindered by the existing devices and
techniques is a spinal discectomy (i.e., removal of intervertebral disc material).
Each disk is composed of an annulus fibrosus, a nucleus pulposus, and a pair of

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end caps which couple the annulus fibrosus and nucleus pulposus. The annulus fibrosus is an annular multi-layered composite structure. Each layer is constructed of fibrous tissue and fibrocartilage with the fibers of each layer ordered and oriented generally in the same direction. The fibers of adjacent layers pass in opposite directions so that when the layers are combined they create a mesh of concentric rings. The central cavity of the annulus houses the nucleus pulposus, which is a semi-gelatinous, highly elastic material. The final components are end caps constructed of thin layers of hyaline cartilage that cover both the top and bottom of each spinal disk. The end caps cover both the annulus fibrosus and the nucleus pulposus and assure that the nucleus pulposus remains within the confines of the annulus fibrosus.

Oftentimes, disks become herniated, or bulge, due to structural damage to the annulus fibrosus. The bulging disk may place pressure on nearby nerves, which can lead to debilitating pain, numbness or muscle weakness. Treatments used to reduce the affects of a damaged disk range from bed rest to spinal fusion. Due to the major shortcomings of those extreme treatments they are often not desirable. A discectomy, either full or partial, can help to balance the burdens and benefits of bed rest and fusion or help prepare the intervertebral site for procedures like fusion.

When a partial discectomy is performed, a portion of the nucleus pulposus of a herniated disc is excised. Partially removing the nucleus material can reduce

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the pressure exerted by the nucleus on the annulus and reduce the bulging. In this procedure, the surgeon must first make an appropriate incision through the skin and other tissue layers, and then typically create an access hole through the herniated annulus (i.e., an annulotomy) to treat the offending tissue. Such access
5 holes are created with a variety of surgical instruments including scalpels, probes, trephines, etc., and the access hole may range in size from 3 to 6 mm in diameter.

Upon entry into the interior annular space, the surgeon removes the offending tissue. The tools typically used are only able to remove small portions
10 of tissue with each approach. As a result, removal of the tissue during a discectomy can take an exorbitant amount of time. In addition, in some cases, when ablation of the vertebral body surfaces adjacent to the disc is required, an additional tool must be used adding additional time and steps to the procedure. The additional time requirement of this procedure gives rise to a need for tools
15 and methods for performing rapid discectomy and end plate ablation.

The present invention is directed at addressing this need and eliminating, or at least reducing, the effects of the shortcomings of the prior art systems as described above.

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SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the prior art by providing, according to a first broad aspect of the present invention, a device for removing body tissue comprising a brush member dimensioned for introduction
5 into a body. The brush member has a plurality of bristle members defining a capacity for carrying body tissue. The brush member is capable of being manipulated within the body to thereby receive body tissue within the brush member such that the body tissue may be carried and thereafter removed from the body.

10

In a further aspect of this device, the capacity for carrying body tissue is defined by at least one of the space between the bristle members and the space between groupings of the bristle members. The bristle members may be grouped to define at least one generally helical space for receiving and carrying body
15 tissue therein, at least one generally axial space for receiving and carrying body tissue therein, and/or at least one generally arcuate space for receiving and carrying body tissue therein.

In another aspect, the bristle members may be disposed in a generally solid
20 configuration with spacing sufficient to receive and carry body tissue between said bristle members. In a further aspect, the brush member has at least one of a generally cylindrical, generally elliptical, and generally polygonal cross-sectional shape. The bristle members may comprise one of metal and plastic and, more

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particularly, at least one of stainless steel wire, carbon-tempered steel wire, non-ferrous wire, and synthetic wire. The bristle members may be generally cylindrical in cross-section with a diameter from 0.002 to 0.100 inches.

5 According to certain aspects, the brush member may be generally cylindrical with a diameter from 0.082 to 1.225 inches. The brush member may also include a stem member extending therefrom for use in manipulating the brush member within said body. In a further aspect, the stem member may be generally cylindrical with a diameter from 0.125 to 0.250 inches. The stem
10 member may also be equipped with a quick-connect coupling for engaging with at least one of a handle member and an extension member. In a further aspect, at least a portion of the bristle members may be retractable within the stem member. The stem member may have a length of from 1 to 24 inches and may include depth indicia.

15

 Among the host of possible applications, the brush member may, according to a further broad aspect, be dimensioned to be introduced into an intervertebral space to receive, carry, and remove intervertebral disc material. In particular, the brush member may be used to remove intervertebral disc material
20 in order to thereafter introduce a spinal implant into the intervertebral space. In another related aspect, the brush member may be dimensioned to be introduced into a vertebral body to receive, carry, and remove osseous material.

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The present invention overcomes the drawbacks of the prior art by providing, according to a second broad aspect of the present invention, a system for removing body tissue comprising a brush member of the type described above in combination with a protector dimensioned to be positioned near an entrance
5 into a target site. The protector establishes a barrier between the brush member and at least a portion of the body tissue adjacent to the entrance. The brush member and protector may be employed to remove body tissue during at least one of a percutaneous surgical procedure and an open surgical procedure.

10 In one further aspect, the protector comprises a cannula dimensioned to extend to the entrance of the target site, wherein the cannula has an inner lumen dimensioned to slideably receive the brush member for passage into the target site. The cannula may include a handle member for directing the cannula to the entrance of the target site. In one aspect, the inner lumen of the cannula and the
15 brush member have approximately the same cross-sectional shape

According to a further embodiment, the brush member includes a stem member, and the system further includes a drive assembly capable of engaging with the stem member for manipulating the brush member within the target site.
20 The drive assembly may comprise one of a powered drive assembly coupled to the stem member and a manual drive assembly coupled to the stem member. The powered drive assembly may comprise a power drill. The manual drive assembly may include a handle member capable of being coupled to the stem member and,

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in a further embodiment, may include an extension member coupled to the handle
and a quick-connect coupling assembly for releasable connection to the stem
member. In either case (powered or manual), the drive assembly may include a
stop member coupled to the stem member for controlling the depth to which the
5 brush member can be advanced into the target site.

According to one aspect of the system, the body tissue adjacent to the
entrance may include at least one of neural tissue, dura tissue, and vasculature
adjacent to the spine. If so, the cannula may include a lip member at a distal end
10 thereof dimensioned to retract at least one of the neural tissue, dura tissue, and
vasculature.

In yet another aspect of the system of the present invention, the protector
comprises a retractor having at least one blade member for establishing a barrier
15 between the brush member and the body tissue adjacent to the entrance to the
target site. The body tissue adjacent to the entrance may include at least one of
neural tissue and dura tissue of the spine. If so, the retractor may include a first
blade member for retracting the neural tissue and a second blade member for
retracting the dura tissue. The first blade member and second blade member may
20 have a fixed or variable angle therebetween. In the latter case, the retractor may
include a handle assembly for varying the angle between the first blade member
and the second blade member.

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Among the host of applications of the system of the present invention, the brush member may, according to a further broad aspect, be dimensioned to be introduced into the intervertebral space to receive, carry, and remove intervertebral disc material. In particular, the brush member may be used to
5 remove intervertebral disc material in order to thereafter introduce a spinal implant into the intervertebral space. In another related aspect, the brush member may be dimensioned to be introduced into a vertebral body to receive, carry, and remove osseous material.

10 The present invention overcomes the drawbacks of the prior art by providing, according to a third broad aspect of the present invention, a method for removing body tissue, comprising the steps of: (a) creating a working channel from a patient's skin to a surgical target site (via percutaneous and/or open techniques); (b) inserting a brush member of the type set forth above into the
15 surgical target site, the brush member having a plurality of bristle members defining a capacity for carrying body tissue; (c) manipulating the brush member within the body to receive body tissue within the brush member; and (d) removing the brush member from the surgical target site.

20 According to various aspects, the surgical target site may be an intervertebral disc space, and the step of inserting a brush member may include, prior to the step of inserting the brush member, positioning a protector near an entrance into the intervertebral disc space for establishing a barrier between the

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brush member and at least one of neural tissue, dura tissue, and vasculature adjacent to the entrance. The protector may comprise a cannula of the type described above and/or retractor (fixed or variable angle) of the type described above.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

10

FIG. 1 is a perspective view of a system for removing body tissue according to one broad aspect of the present invention;

FIG. 2 is a side view of a cannula assembly forming part of the system for removing body tissue shown in FIG. 1;

15

FIGS. 3 and 4 are side and end views, respectively, of a brush member and adapter member forming part of the tissue removal system of FIG. 1;

20

FIG. 5 is a side view of an extension member forming part of the tissue removal system shown in FIG. 1;

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FIGS. 6 and 7 are perspective and cross-sectional views, respectively, of a stopper assembly forming part of the tissue removal system shown in FIG. 1;

FIGS. 8 and 9 are side and top views, respectively, of the tissue removal system of FIG. 1 in use performing a discectomy;

FIGS. 10 and 11 are perspective and side views, respectively, of a retractor forming an alternate aspect of the tissue removal system shown in FIG. 1 (without the cannula assembly 14);

FIG. 12 is a perspective view of a fixed angle tissue retractor according to one embodiment of the present invention;

FIG. 13 is a perspective view of a variable angle tissue retractor according to further embodiment of the present invention;

FIGS. 14 and 15 are top views showing the variable angle tissue retractor of FIG. 13 with the blade members generally closed (FIG. 14) and generally open (FIG. 15);

FIGS. 16 and 17 are top views of trays forming a kit according to one embodiment of the present invention;

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FIGS. 18-23 are side views showing various alternate configurations of the brush member according to the present invention;

FIG. 24 are cross-sectional views illustrating several manners of providing the brush member;

FIG. 25 is a top view of an alternate brush member configuration, disposed along a curved stem member; and

FIG. 26 is a top view of an alternate embodiment having multiple brush members and multiple stem members.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The

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systems disclosed herein boast a variety of inventive features and components that warrant patent protection, both individually and in combination.

The present invention overcomes the shortcomings of tissue ablation techniques of the prior art by employing a brush member having a plurality of bristle members defining a capacity for carrying body tissue. The capacity for carrying body tissue is based on the spacing between the individual bristle members and/or the spacing between one or more groups of bristle members. While the present invention is described below within the context of removing body tissue relating to the spine (i.e. intervertebral disc material and/or osseous material), it is to be readily appreciated that the present invention may be used in any number of different medical procedures. These may include, but are not necessarily limited to, knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, capsulectomy in the knee, complete or partial resection of internal organs, tumors and lesions. As used herein, the term "body tissue" includes any tissue present in a living or dead body, including but not limited to tissue involved in the aforementioned list of medical procedures (including intervertebral disc material, cancellous and cortical bone, and fatty tissues).

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FIG. 1 illustrates a system 10 for removing body tissue according to a first broad aspect of the present invention. The system 10 includes a brush member 12 and a cannula assembly 14. Although described immediately below within the context of use with the cannula assembly 14, it is to be understood at the outset
5 that the brush member 12 (including all the variations shown and described herein -- and their equivalents) forms an independently patentable aspect of the present invention. As will be described in greater particularity below, this is based on the primary feature of providing the brush member 12 having a plurality of bristle members defining a capacity for carrying body tissue, wherein the brush member
10 12 is capable of being manipulated within the body to thereby receive body tissue within the brush member 12 such that the body tissue may be carried and thereafter removed from the body. The capacity for carrying body tissue is defined by at least one of the space between the individual bristle members forming the brush member 12 and the space between groupings of bristle
15 members forming the brush member 12.

With combined reference to FIGS. 1-2, the cannula assembly 14 includes a cannula member 16 and a handle member 18. The cannula member 16 has an inner lumen 20 dimensioned to pass the brush member 12 therethrough en route
20 to a surgical target site within a body. In one aspect of the present invention, the surgical target site may be one of the intervertebral disc space and an intravertebral body space. Importantly, the distal end of the cannula member 16 (opposite the handle member 18) serves to form a protective barrier between the

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brush member 12 and tissues adjacent to the surgical target site. Within the context of spinal applications, such tissues may include, but are not necessarily limited to, neural structures (i.e. exiting nerve roots) and dura tissue (during posterior and/or postero-lateral access to the spine) and vasculature (during
5 anterior access to the spine). To further protect against inadvertent contact with such adjacent tissues (including pinching such structures), the cannula assembly 14 is equipped a lip member 22 capable of preventing such tissues from migrating into the distal opening of the cannula 16.

10 With reference to FIGS. 1 and 3-4, the brush member 12 is provided, by way of example only, having its bristles disposed in a dual spiral or helical grouping 24 along a stem member 26. This helical configuration 24 of the bristles creates a generally helical space 28 extending along the length (L_B) of the brush member 12. This helical space 28, along with the space between the individual
15 bristles forming the helical grouping 24, defines a carrying capacity within the brush member 12 for the removal of body tissue. In a preferred embodiment, the length (L_B) of the brush member 12 may range from 0.25 to 4.0 inches and the diameter (D_B) of the brush member 12 may range from 0.082 to 1.225 inches.

The bristles may be constructed from a number of materials that have
20 sufficient strength to avoid shedding or dislodging of the bristles from the stem 26 during use and of proven safety in medical applications. Such bristle materials may include, by way of example, metal and plastic and, more particularly, stainless steel wire, carbon-tempered steel wire, non-ferrous wire, and synthetic

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materials (such as nylon or other plastics). In a preferred embodiment, the individual bristles are generally cylindrical, each having a diameter ranging from 0.002 to 0.100 inches. Although not shown, the bristles may also be provided having a square or other polygonal cross-section (depending on the method of manufacture - which may include drawing, extrusion or molding) without departing from the scope of the present invention.

The stem member 26 is a generally rigid member that extends, according to one embodiment, away from the brush member 12 for connection to a quick-connect adapter 30. The stem member 26 may be provided having a diameter (Ds) ranging from 0.125 to 0.250 inches and a length ranging from 1 to 24 inches. The quick-connect adapter 30 enables the stem member 26 to be quickly coupled or de-coupled from a manual drive assembly 32 to be described below. The quick connect adapter 30 is generally cylindrical with a connector portion 34 on its proximal end. The distal end of the quick connect adapter 30 may be coupled to the stem member 26 by crimping or by any mechanical connection that provides sufficient strength to withstand torsional forces during rotation of the brush member 12. The male connector portion 34 includes a flat surface 34 that provides a bearing surface that transmits rotation between the brush member 12 and the manual drive assembly 32, and a concentric channel 53 that is engaged by a retractable feature in a mating device that prevents axial movement between the quick connect adapter 30 and the a mating device. It should be appreciated that there are many known connection mechanisms that may be substituted without

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departing from the scope of the present invention, including but not limited to a Jacob's adapter.

Turning to FIGS. 1 and 5, the manual drive assembly 32 includes, by way of example, an extension adapter 40 having a female quick-connect collet 42 at its distal end and a male connecting portion 44 at its proximal end. The female quick connect collet 42 is of known construction and functions to couple the extension adapter 40 to the quick-connect adapter 30. The male connecting portion 44 is of similar construction to the corresponding connecting portion 34 of the quick connect adapter 30 and, as such, need not be described again here, except to point out that the connecting portion 44 of the extension adapter 40 is, in a preferred embodiment, to be coupled to a manual handle (not shown) such that a surgeon may impart rotational force on the brush member 12 to effectuate the tissue removal of the present invention. According to an alternate embodiment, the connecting portion 44 may be coupled to a power drill (thus forming a powered drive mechanism according to the present invention).

The extension adapter 40 may be provided with certain depth management features to control or manage the extent to which the brush member 12 is introduced into the target surgical site. In one embodiment, these depth management features may include indicia 46 disposed along the length of the extension adapter 40 (denoting, by way of example, a depth ranging from 0 to 50 mm) and a plurality of notches 48. These depth management features are

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particularly suited for use with a stopper assembly 50 shown generally in FIG. 1 and in detail in FIGS. 6-7.

The stopper assembly 50 includes a stop member 52, a detent member 54,
5 a spring 56, and a locking pin 58. The stop member 52 includes an aperture 60 dimensioned to receive the extension member 40, as well as a side aperture 62 for receiving the detent member 54. The detent member 54 includes a locking pin slot 64, an engagement aperture 66, and an extension 68. The slot 64 allows the locking pin 58 to travel therein to control the inward and outward travel of the
10 detent member 54 within the stop member 52. The aperture 66 includes an enlarged region 70 and an engagement ridge 72 (hence the "semi-constrained" terminology). When the detent 54 is pushed into the stop member 52 (by urging against the spring 56), the enlarged region 70 is moved into general coaxial alignment with the aperture 60 such that the extension adapter 40 may be passed
15 through the stop member 52. Once positioned at a desired location along the notched region 48 of the extension adapter 40, the detent member 54 may be released such that the engagement ridge 72 will be disposed within one of the notches 48 and thereby restrict the movement of the extension adapter 40 relative to the stop member 52. In a preferred embodiment, the stop member 52 does not
20 restrict either rotation of the brush member 12 or translation in the proximal direction. As a result, the brush member 12 is limited to a depth that can be predetermined while still allowing rotation and limited back and forth motion.

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With reference to FIGS. 8-9, the tissue removal system 10 will now be described, by way of example only, in use within in the context of a discectomy procedure despite its general utility in any of a variety of tissue removal procedures. First, a working channel is formed between the patient's skin and the surgical target site, which in this case is an intervertebral disc space. The working channel be created via a traditional "open" techniques or a percutaneous or "minimal access" technique. With the working channel created, the cannula 16 may be inserted such that its distal end (with the lip member 22) is disposed adjacent to or in the generally proximity of the annulus. In a preferred embodiment, the lip member 22 may be used to prevent any surrounding tissue (such as exiting nerve roots and/or dura tissue in the case of the posterolateral approach shown best in FIG. 9) from migrating into the distal opening of the cannula 16. An annulotomy device of known construction may be extended to the disc through the cannula 16 to remove a section of the disc annulus.

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Thereafter, the discectomy brush 12 may be extended into the disc nucleus via the cannula 16 and disc annulus. The brush member 12 may then be rotated, manually or by power means such as a drill, to remove disc material. Depending on the diameter of the brush member 12 and the distance between the adjacent vertebrae, the discectomy brush 12 may be used to remove tissue as well as ablate or partially decorticate the surfaces of the adjacent vertebrae. The brush member 12 may then be removed and may be discarded or cleaned depending on the brush

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material. In one embodiment, the brush is comprised of plastic and another of stainless steel.

After removal of such disc material and, optionally, preparation of the vertebral endplates, any of a variety of spinal implants may be inserted into the space created by the discectomy brush. These spinal implants may include, but are not necessarily limited to, allograft products, ceramic spacers, and total disc replacement devices. Whatever the implant, it should ideally be inserted into this space via the cannula 16. The annulus opening may then be closed (through any known means, such as sutures or patch devices or sealing compounds) and then the cannula 16 removed. It should be readily understood that anterior, extreme lateral, posterolateral or posterior approaches may be utilized using the principles of the present invention.

FIGS. 10-11 illustrate another broad aspect of the present invention, wherein a retractor 80 is provided (as opposed to the cannula assembly 16 described above) for the purpose of establishing a protective barrier between the brush member 12 and the tissues adjacent to the surgical target site (again, the intervertebral disc space). To accomplish this, the retractor 80 provides a pair of retractor blade 82, 84, which collectively form a generally "V" shaped construct capable of preventing the exiting nerve root (via blade 82) and the dura tissue (via blade 84) from migrating into a region that might otherwise result in the unwanted contact between the brush member 12 and these tissues. To facilitate this, each

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blade member 82, 84 is preferably equipped with a lip member 83 similar to lip member 22 of the cannula 16. As shown in FIG. 12, these blade members 82, 84 may be positioned relative to the surgical target site by virtue of an elongate curved shaft 86 coupled to a handle member 88. In one embodiment, the blade members 82, 84 have a fixed angle relative to one another ranging from between 50 and 75 degrees.

In an alternate embodiment shown in FIGS. 13-15, the retractor 80 may have blade members 82, 84 that are variable angle relative to one another. To accomplish this, a handle assembly 90 is provided having a pair of gripping elements 92, 94 which, upon manipulation towards (FIG. 14) and away (FIG. 15) from one another serve to increase and decrease, respectively, the angle between the blade members 82, 84. A shaft 85 extends between the gripping elements 92, 94 for independently coupling the blade members 82, 84 to one of the gripping elements 92, 94. A locking feature may be optionally be provided by equipping the first gripping element 92 with an arcuate, ribbed engagement element 96 which cooperates with a trigger member 98 coupled to the second gripping element 94. A spring 100 is disposed between the gripping elements 92, 94 and over a portion of the engagement element 96 to aid in the locking and unlocking of the handle assembly 90. In one embodiment, the angle between the blade members 82, 84 may be varied between 0 and 180 degrees and, more preferably, 0 to 90 degrees. The ability to close the angle between the blades 82, 84 (that is, to an angle of approximately 0 to 30 degrees) is helpful in that it may aid in

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placing the blades 82, 84 in proper position to form the barrier between the surrounding tissue and the brush member 12, such as by being introduced in the closed or reduced angle and thereafter opening the blades 82, 84 to thereby more gently move the adjacent structures aside.

5

With reference to FIGS. 16-17, the tissue removal system 10 of the present invention may be provided in any number of suitable fashions, including the kit fashion shown comprising a first tray 110 and a second tray 112. By way of example only, the tray 110 may be provided having a plurality of brush members 12 of varying size and length to accommodate the particular surgical need or procedure. Tray 110 may also include components of the given drive mechanism, such as a pair of extension members 40 (for coupling to the quick coupling adapters 30 attached to the brush members 12); a pair of stopper assemblies 50, a handle assembly 51 (for quick-connect coupling to the extension member 40), and a pair of retractors 80 (in this embodiment, the fixed angle configuration). Tray 112 may include a plurality of cannula assemblies 14 having cannulas 16 with inner lumens having the same or similar diameters as the brush members 12 contained in tray 110. Providing the tissue removal system 10 of the present invention in this fashion is convenient and offers significant time savings and flexibility in tailoring the system 10 depending upon the given surgical procedures.

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As mentioned above, the brush member 12 forms an independent and significant feature of the present invention based on its capacity to carry body tissue both within the bristles of the brush, as well as between the groupings of bristles. Although shown above with reference to a dual spiral configuration, it is to be readily appreciated that the brush member 12 may be provided in any number of suitable fashions without departing from the scope of the present invention. For example, the brush member 12 may be provided having a single spiral bristle grouping 24 (see FIG. 18) defining a generally helical space 28 for receiving and carrying body tissue, a generally solid configuration (see FIG. 19) wherein the bristles have sufficient spacing therebetween to receive and carry body tissue, one or more radially extending bristle groupings 24 (FIGS. 20-21) defining at least one generally arcuate space 28 for receiving and carrying body tissue, and one or more axially disposed bristle groupings 24 (FIGS. 22-23) defining at least one generally axial space 28 for receiving and carrying body tissue. Moreover, the cross-sectional shape of the brush member 12 may vary from the generally circular cross-section of the cylindrical brush member 12 shown above, to any of a variety of polygonal cross-sections, including but not limited to those shown in FIG. 24.

20 In a further aspect of the present invention, it is contemplated that the bristles forming the brush member 12 may be retractable toward the stem member 26 allowing for the brush diameter to be increased after insertion into the material to be excised. That feature may be accomplished by construction of the brush

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portion 11 from a material such as Nitinol or other "memory metal" or through a mechanical or electro-mechanical mechanism. It is similarly contemplated to (as shown in FIG. 25) provide the brush member 12 formed along a curved (or possibly rounded) stem member 26 for manual or automated manipulation within the target site (such as back-and-forth and/or side-to-side), as well as (as shown in FIG. 26) provide a plurality of brush members 12, each having a stem member 26 capable of independent manipulation (such as via rotation) and/or unison operation (moving the entire configuration back-and-forth and/or side-to-side) to effectuate body tissue removal.

10

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

15

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CLAIMS

We claim:

1. A device for removing body tissue, comprising:
a brush member dimensioned for introduction into a body, said brush member
5 having a plurality of bristle members defining a capacity for carrying body tissue,
said brush member capable of being manipulated within said body to thereby
receive body tissue within said brush member such that said body tissue may be
carried and thereafter removed from said body.
- 10 2. The device of claim 1, wherein said capacity for carrying body tissue is
defined by at least one of the space between said bristle members and the space
between groupings of said bristle members.
3. The device of claim 1, wherein said bristle members are grouped to define
15 at least one generally helical space for receiving and carrying body tissue therein.
4. The device of claim 1, wherein said bristle members are grouped to define
at least one generally axial space for receiving and carrying body tissue therein.
- 20 5. The device of claim 1, wherein said bristle members are grouped to define
at least one generally arcuate space for receiving and carrying body tissue therein.

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6. The device of claim 1, wherein said bristle members are disposed in a generally solid configuration with spacing sufficient to receive and carry body tissue between said bristle members.
- 5 7. The device of claim 1, wherein said brush member has at least one of a generally cylindrical, generally elliptical, and generally polygonal cross-sectional shape.
8. The device of claim 1, wherein said brush member is generally cylindrical
10 and has a diameter from 0.082 to 1.225 inches.
9. The device of claim 1, including a stem member extending from said brush member for use in manipulating said brush member within said body.
- 15 10. The device of claim 9, wherein said stem member is generally cylindrical and has a diameter from 0.125 to 0.250 inches.
11. The device of claim 3, wherein said stem member is equipped with a quick-connect coupling for engaging with at least one of a handle member and an
20 extension member.
12. The device of claim 9, wherein at least a portion of said bristle members are retractable within said stem member.

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13. The device of claim 9, wherein said stem member has a length of from 1 to 24 inches and includes depth indicia.

5 14. The device of claim 1, wherein said bristle members comprise one of metal and plastic.

15 15. The device of claim 1, wherein said bristle members comprise one of stainless steel wire, carbon-tempered steel wire, non-ferrous wire, and synthetic
10 wire.

16. The device of claim 1, wherein said bristles members are generally cylindrical in cross-section with a diameter from 0.002 to 0.100 inches.

15 17. The device of claim 1, wherein said brush member is dimensioned to be introduced into an intervertebral space to receive, carry, and remove intervertebral disc material.

20 18. The device of claim 17, wherein said brush member is used to remove intervertebral disc material in order to thereafter introduce a spinal implant into said intervertebral space.

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19. The device of claim 1, wherein said brush member is dimensioned to be introduced into a vertebral body to receive, carry, and remove osseous material.

20. A system for removing body tissue, comprising:

- 5 a brush member dimensioned for introduction into a target site within a body, said brush member having a plurality of bristle members defining a capacity for carrying body tissue, said brush member capable of being manipulated within said body to thereby receive body tissue within said brush member such that said body tissue may be carried and thereafter removed from said body; and
- 10 a protector dimensioned to be positioned near an entrance into said target site, said protector establishing a barrier between said brush member and at least a portion of the body tissue adjacent to said entrance.

21. The system of claim 20, wherein said protector comprises a cannula

15 dimensioned to extend to said entrance of said target site, said cannula having an inner lumen dimensioned to slideably receive said brush member for passage into said target site.

22. The system of claim 21, wherein said cannula includes a handle member

20 for directing said cannula to said entrance of said target site.

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23. The system of claim 22, wherein said brush member includes a stem member, and further comprising a drive assembly capable of engaging with said stem member for manipulating said brush member within said target site.

5 24. The system of claim 23, wherein said drive assembly comprises one of a powered drive assembly coupled to said stem member and a manual drive assembly coupled to said stem member.

10 25. The system of claim 24, wherein said powered drive assembly is a power drill.

26. The system of claim 24, wherein said manual drive assembly includes a handle member capable of being coupled to said stem member.

15 27. The system of claim 26, wherein said manual drive assembly includes an extension member coupled to said handle and a quick-connect coupling assembly for releasable connection to said stem member.

20 28. The system of claim 24, wherein said drive assembly includes a stop member coupled to said stem member for controlling the depth to which said brush member can be advanced into said target site.

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29. The system of claim 21, wherein said body tissue adjacent to said entrance includes at least one of neural tissue, dura tissue, and vasculature adjacent to the spine, and wherein said cannula includes a lip member at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and
5 vasculature.

30. The system of claim 21, wherein said inner lumen of said cannula and said brush member have approximately the same cross-sectional shape.

10 31. The system of claim 20, wherein said protector comprises a retractor having at least one blade member for establishing a barrier between said brush member and said body tissue adjacent to said entrance.

15 32. The system of claim 31, wherein said body tissue adjacent to said entrance includes at least one of neural tissue and dura tissue of the spine, and wherein said retractor includes a first blade member for retracting said neural tissue and a second blade member for retracting said dura tissue.

20 33. The system of claim 32, wherein said first blade member and second blade member have a fixed angle therebetween.

34. The system of claim 32, wherein said first blade member and second blade member have a variable angle therebetween.

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35. The system of claim 34, wherein said retractor includes a handle assembly for varying said angle between said first blade member and said second blade member.

5

36. The system of claim 20, wherein said target site is an intervertebral space, and wherein brush member is dimensioned to be introduced into said intervertebral space to receive, carry, and remove intervertebral disc material.

10

37. The system of claim 36, wherein said brush member is used to remove intervertebral disc material in order to thereafter introduce a spinal implant into said intervertebral space.

15

38. The system of claim 20, wherein said target site is a vertebral body, and wherein said brush member is dimensioned to be introduced into said vertebral body to receive, carry, and remove osseous material.

20

39. The system of claim 20, wherein said brush member and protector may be employed to remove body tissue during at least one of a percutaneous surgical procedure and an open surgical procedure.

40. A method for removing body tissue, comprising the steps of:
creating a working channel from a patient's skin to a surgical target site;

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inserting a brush member into said surgical target site, said brush member
having a plurality of bristle members defining a capacity for carrying body tissue;
manipulating said brush member within said body to receive body tissue
within said brush member; and
5 removing said brush member from said surgical target site.

41. The method of claim 40, wherein said step of creating a working channel
to the surgical target site is accomplished via at least one of a percutaneous
surgical procedure and an open surgical procedure.

10

42. The method of claim 40, wherein said surgical target site is an
intervertebral disc space, and wherein said step of inserting a brush member
includes, prior to said step of inserting said brush member, positioning a protector
near an entrance into said intervertebral disc space for establishing a barrier
15 between said brush member and at least one of neural tissue, dura tissue, and
vasculature adjacent to said entrance.

43. The method of claim 42, wherein said protector comprises a cannula
dimensioned to extend to said entrance of said intervertebral disc space, said
20 cannula having an inner lumen dimensioned to slideably receive said brush
member for passage into said intervertebral disc space.

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44. The method of claim 40, wherein said brush member includes a stem member, and further including the step of providing a drive assembly capable of engaging with said stem member for manipulating said brush member within said target site.

5

45. The method of claim 44, wherein said drive assembly comprises one of a powered drive assembly coupled to said stem member and a manual drive assembly coupled to said stem member.

10

46. The method of claim 45, wherein said powered drive assembly is a power drill.

47. The method of claim 45, wherein said manual drive assembly includes a handle member capable of being coupled to said stem member.

15

48. The method of claim 47, wherein said manual drive assembly includes an extension member coupled to said handle and a quick-connect coupling assembly for releasable connection to said stem member.

20

49. The method of claim 45, wherein said drive assembly includes a stop member coupled to said stem member for controlling the depth to which said brush member can be advanced into said target site.

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50. The method of claim 43, wherein said cannula includes a lip member at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine.
- 5 51. The method of claim 43, wherein said inner lumen of said cannula and said brush member have approximately the same cross-sectional shape.
52. The method of claim 42, wherein said protector comprises a retractor having at least one blade member for establishing a barrier between said brush
10 member and said body tissue adjacent to said entrance.
53. The method of claim 52, wherein said body tissue adjacent to said entrance includes at least one of neural tissue and dura tissue of the spine, and wherein said retractor includes a first blade member for retracting said neural
15 tissue and a second blade member for retracting said dura tissue.
54. The method of claim 53, wherein said first blade member and second blade member have a fixed angle therebetween.
- 20 55. The method of claim 53, wherein said first blade member and second blade member have a variable angle therebetween.

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56. The method of claim 55, wherein said retractor includes a handle assembly for varying said angle between said first blade member and said second blade member.
- 5 57. The method of claim 40, wherein said surgical target site is a vertebral body, and wherein said brush member is dimensioned to be introduced into said vertebral body to receive, carry, and remove osseous material.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/28926

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/00

US CL : 606/791

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 6,099,309 A (CARDARELLI) 08 August 2000 (08.08.2000), see entire document.	1,2,6-10,14,15,17-20,36-39
X,P — Y,P	US 6,423,078 B1 (BAYS et al.) 23 July 2002 (23.07.2002), see entire document.	16 1,2,6,7,9,13,17-25,28-31,36-39
X,P — Y,P	US 2002/0016583 A1 (CRAGG) 07 February 2002 (07.02.2002), see paragraph 140.	8,10,14-16 1,2,6,7,9,17-19,40,41,44-46,57
X — Y	US 5,355,547 A (FITJER) 18 October 1994 (18.10.1994), see entire document.	8,10,14-16 1,2,4-8,17-19 14-16



Further documents are listed in the continuation of Box C.



See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" documents referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

26 March 2003 (26.03.2003)

Date of mailing of the international search report

23 MAY 2003

Name and mailing address of the ISA/US

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Box PCT

Washington, D.C. 20231

Facsimile No. (703)305-3230

Authorized officer

David O. Reip

Diane Smith for

Telephone No. (703) 305-3333

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

PCT/US02/28926

Continuation of B. FIELDS SEARCHED Item 1:

606/79,84,85,96,131,159,167,170,172,180

435/125,142

Continuation of B. FIELDS SEARCHED Item 3:

EAST

brush, bristle, cannula, guard, shield

INTERNATIONAL SEARCH REPORT

PCT/US02/28926

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,108,162 A (CHIKASHIGE et al.) 22 August 1978 (22.08.1978) see entire document.	1-7,9,13,17-19 <u>8,10</u>

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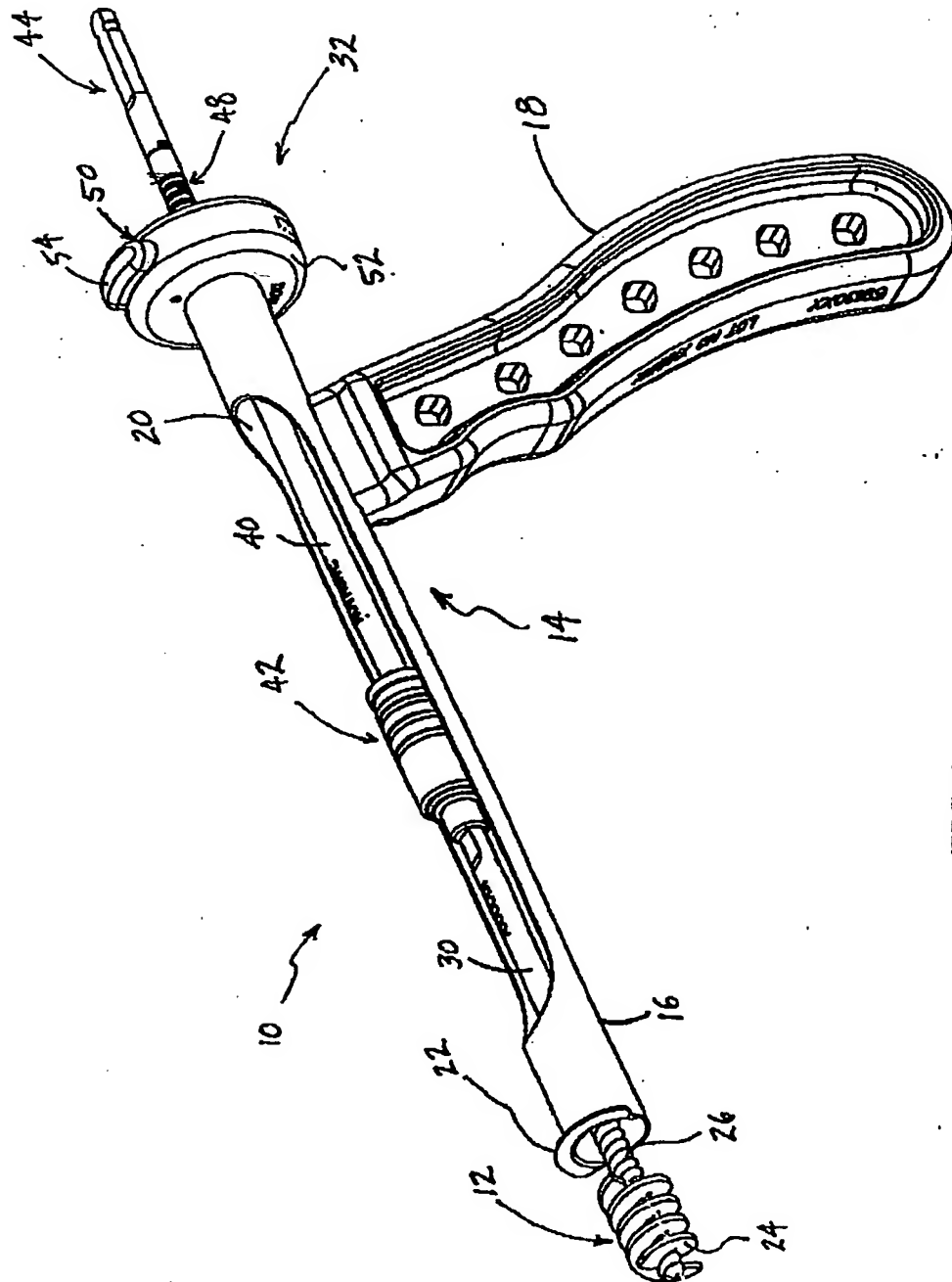
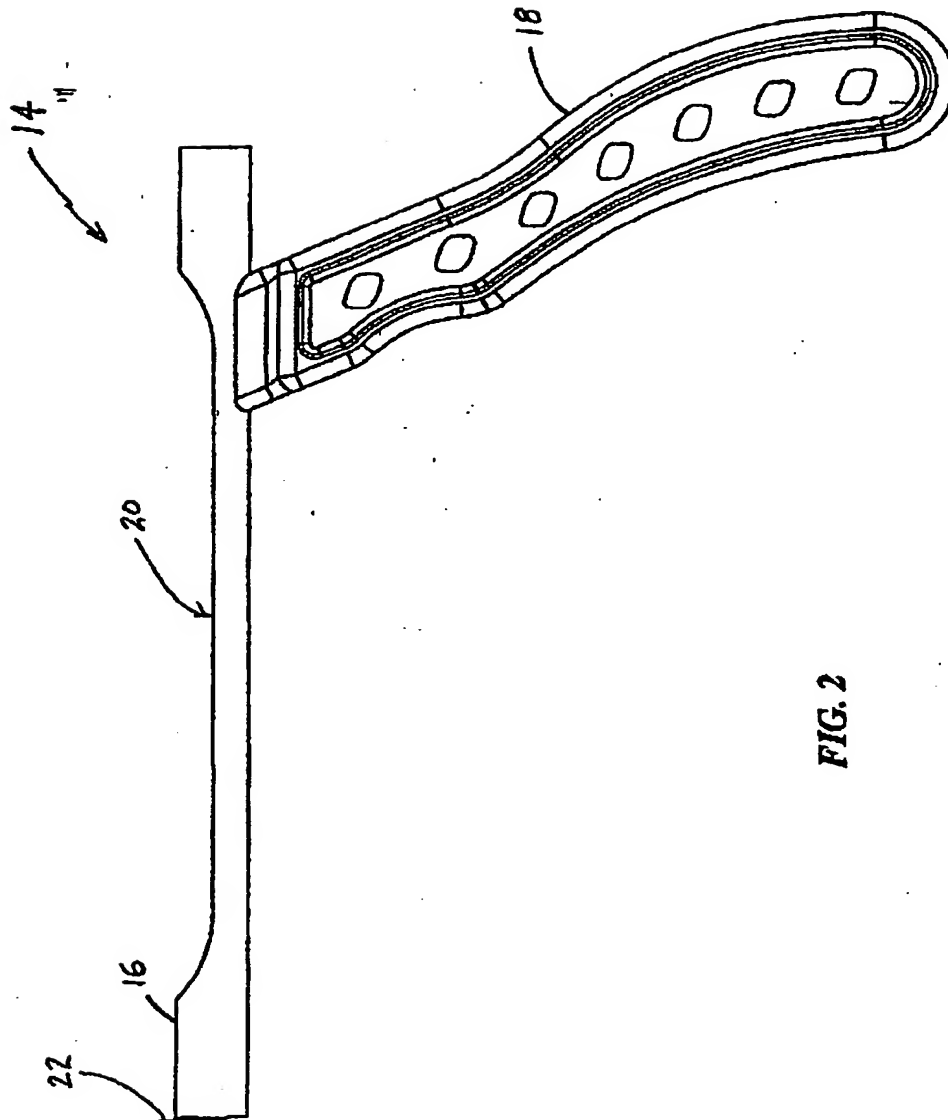


FIG. 1

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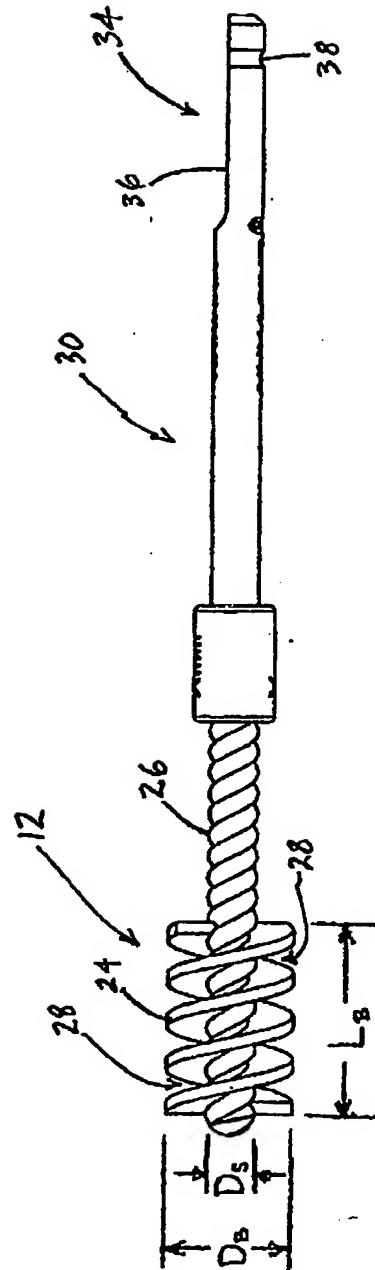


FIG. 3

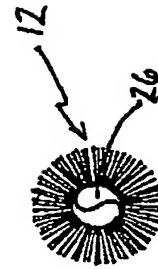


FIG. 4

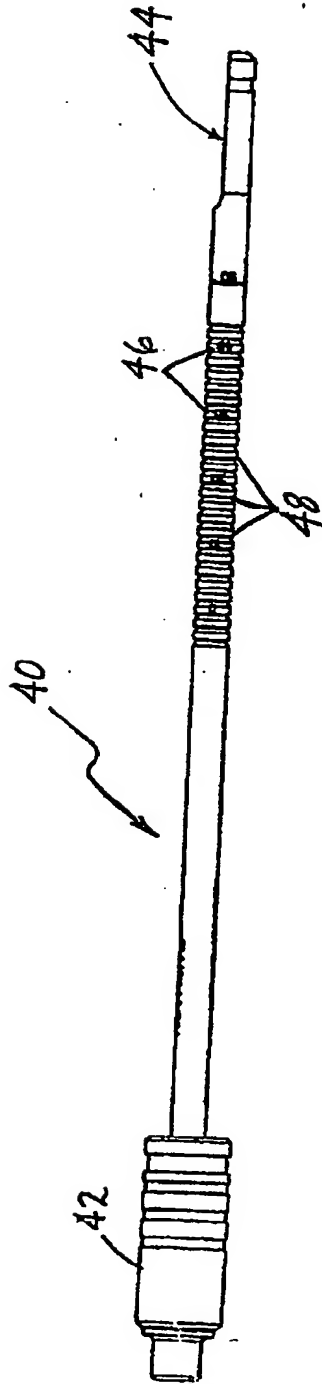


FIG. 5

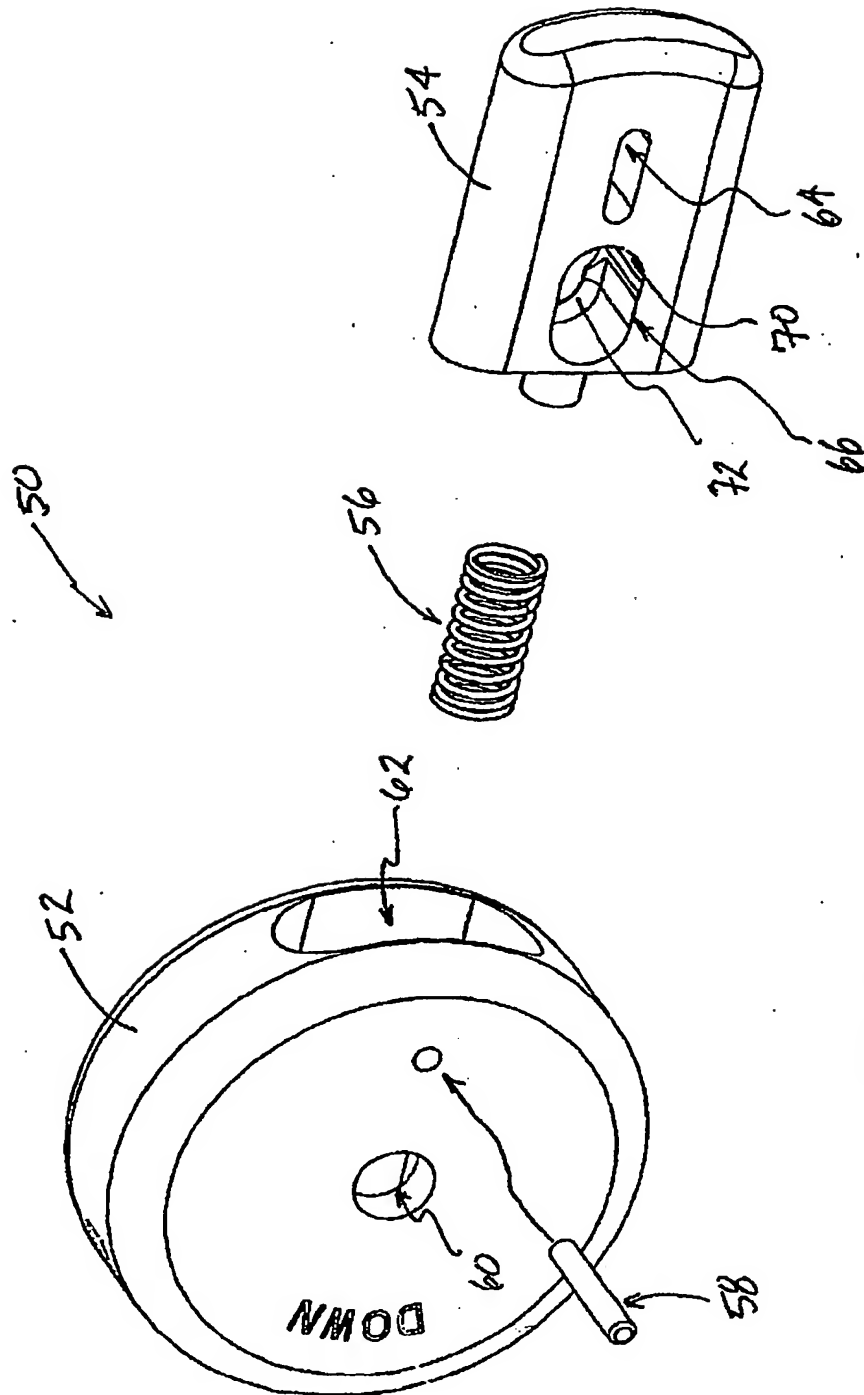


FIG. 6

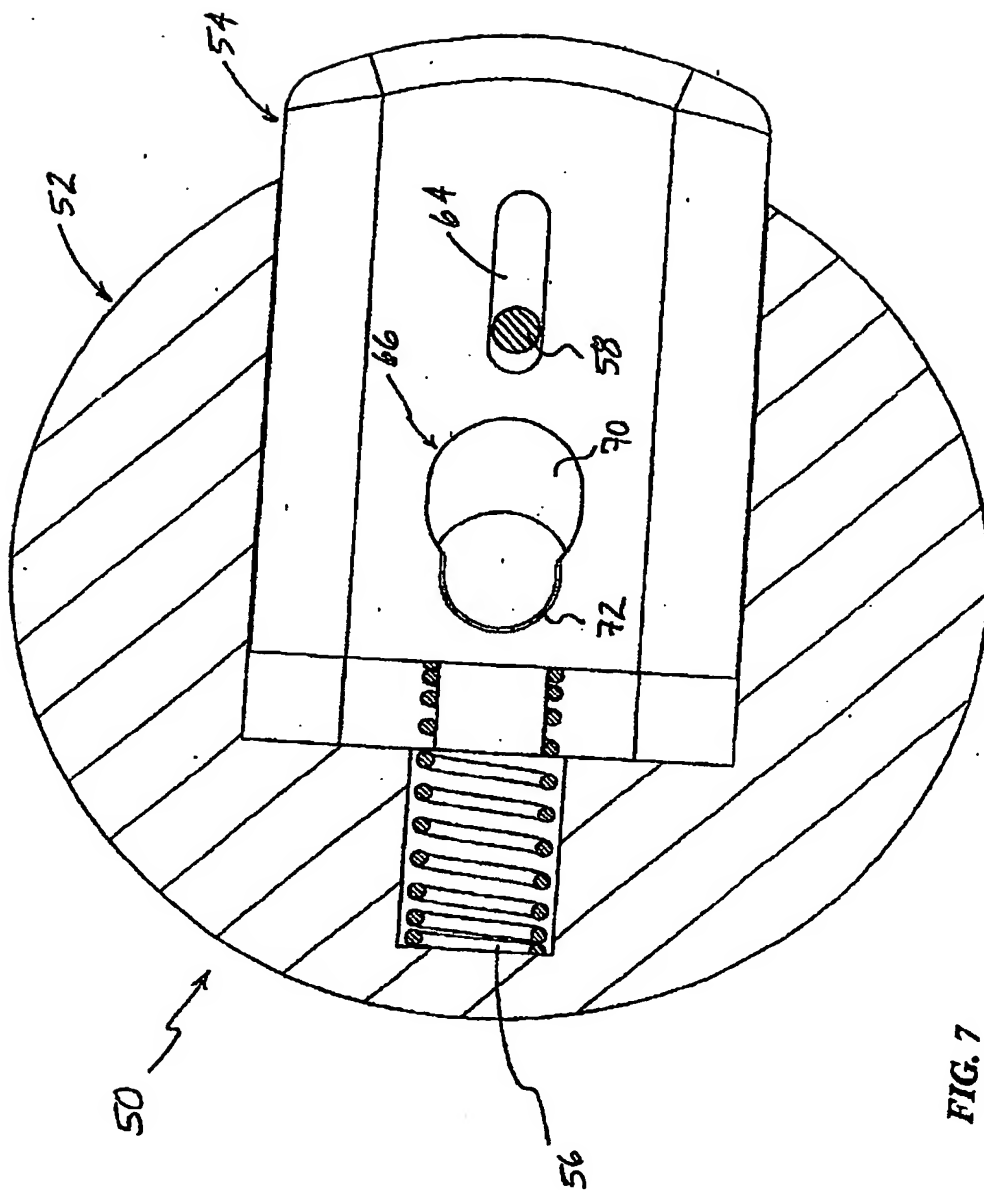
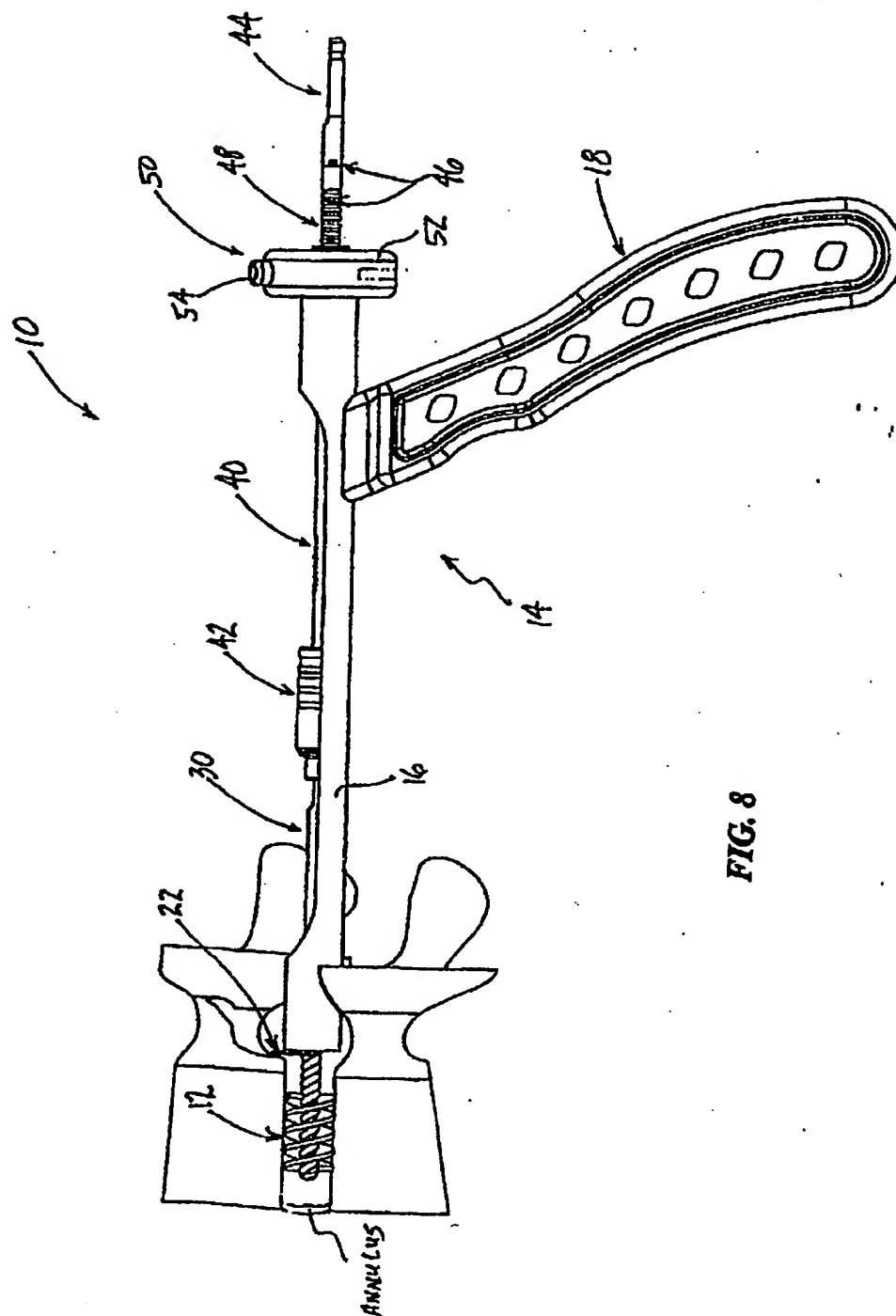
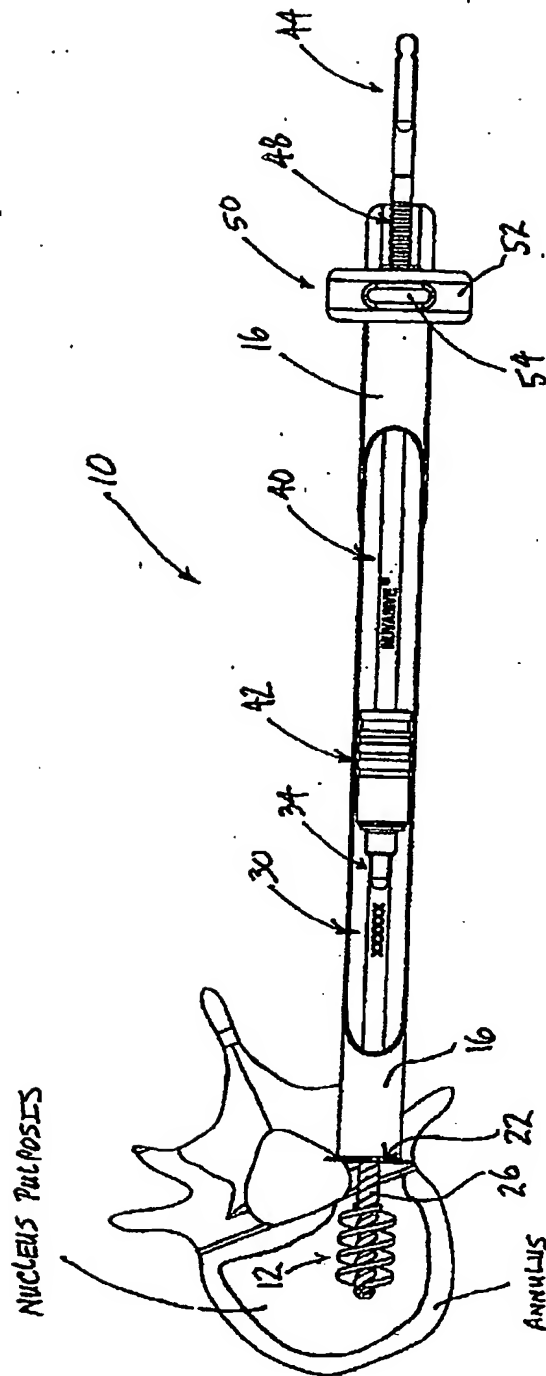


FIG. 7





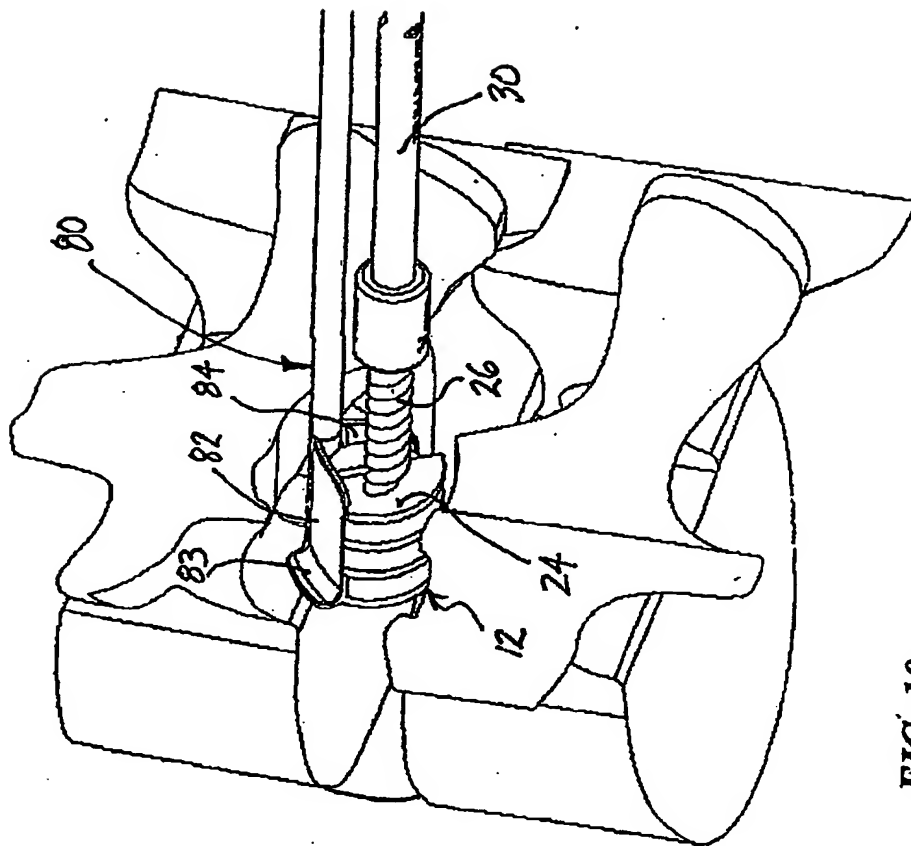
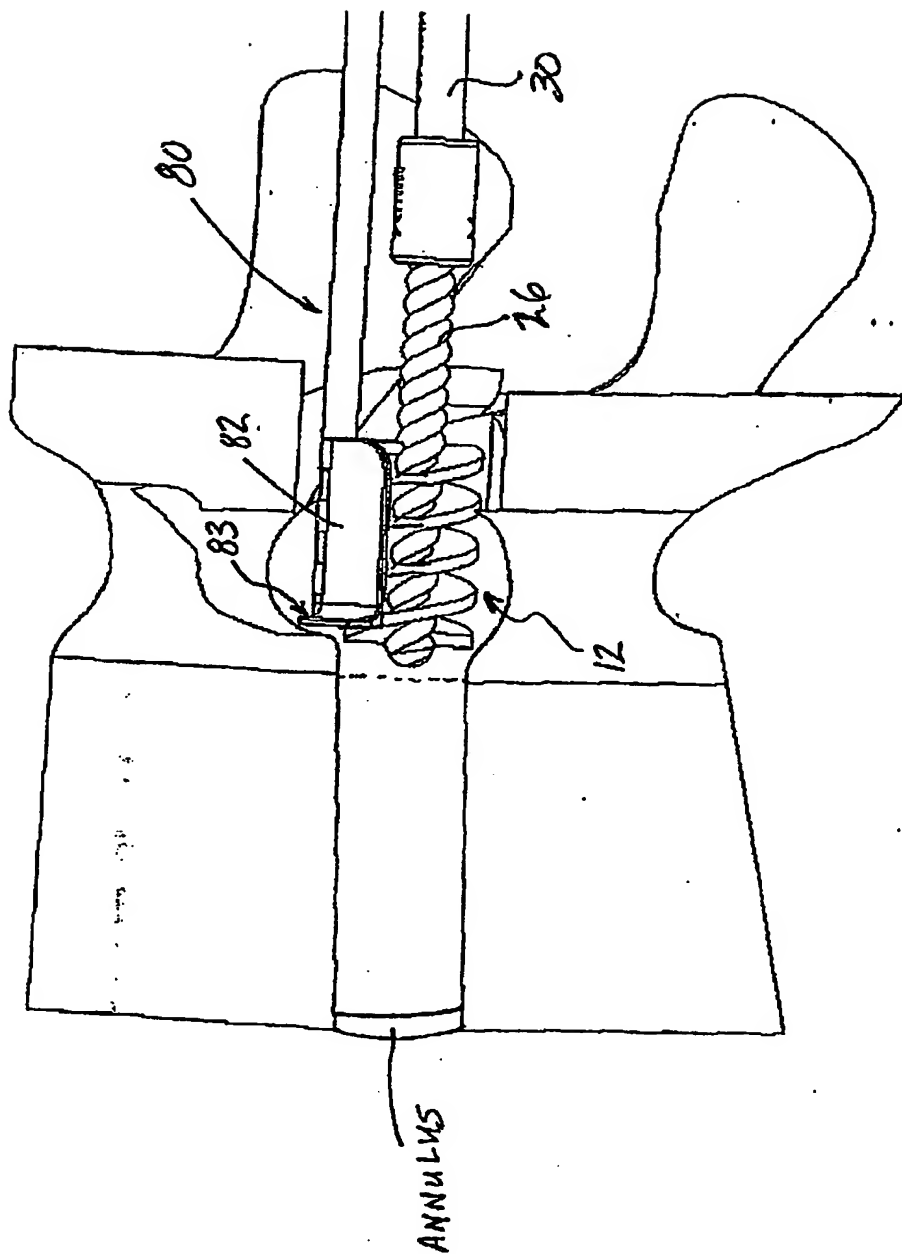
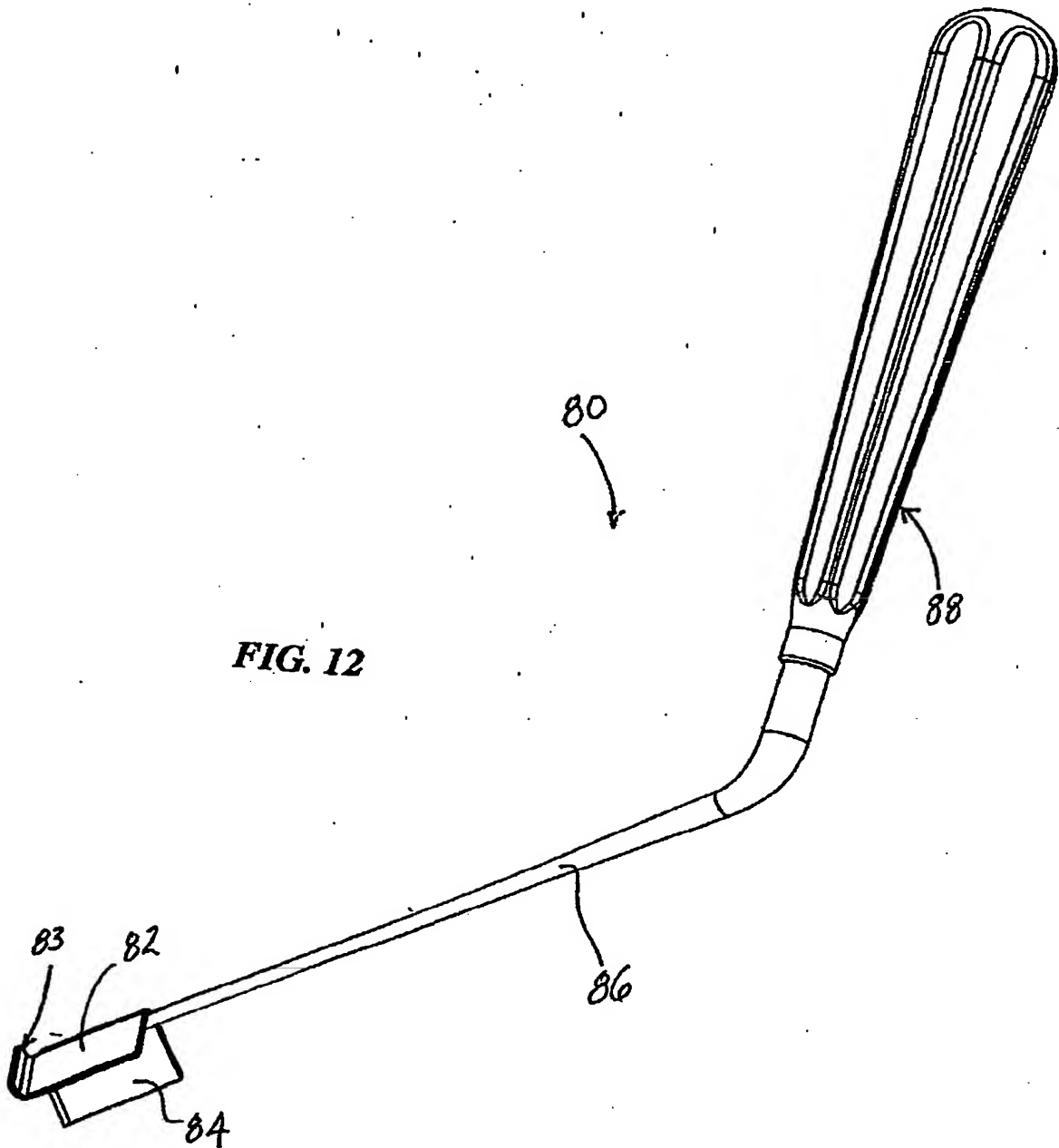


FIG. 10





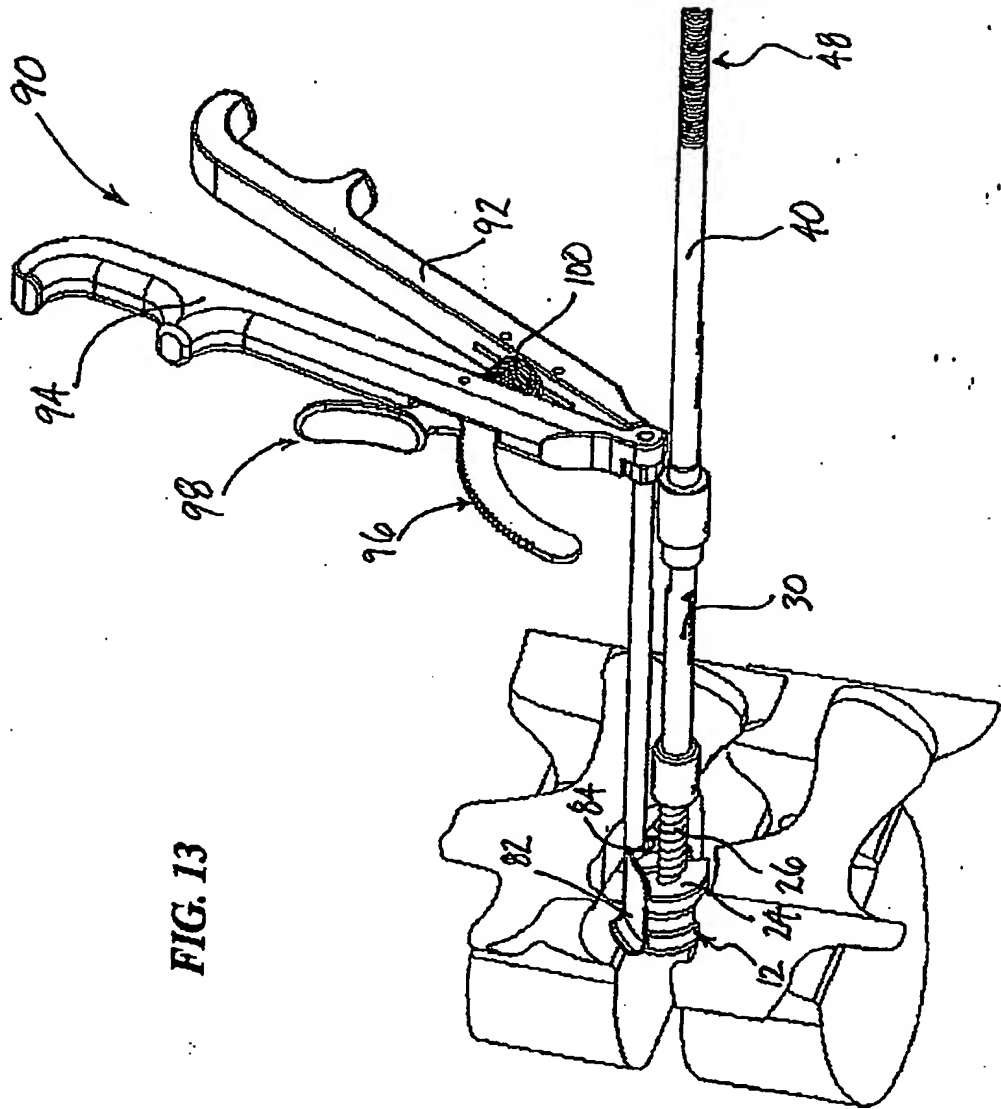


FIG. 13

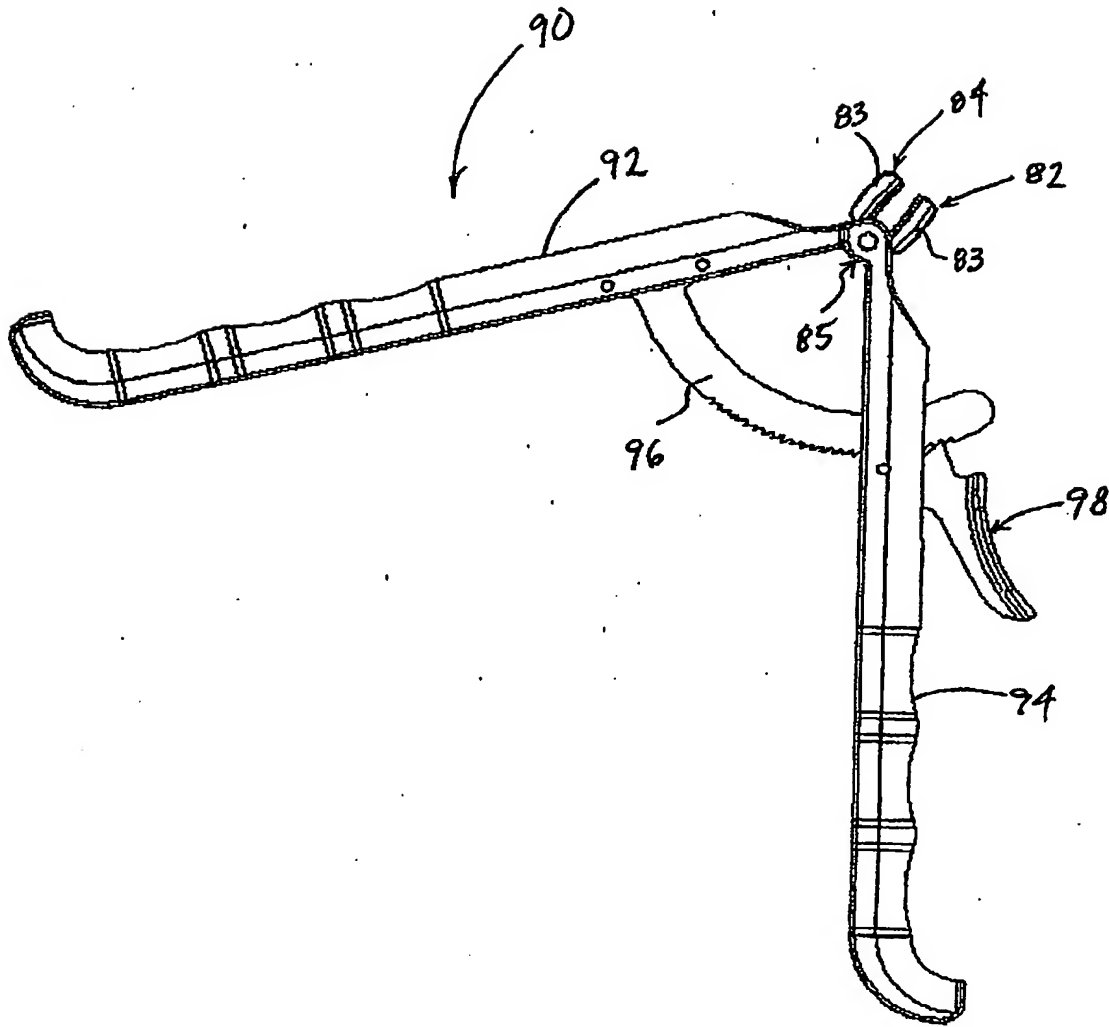
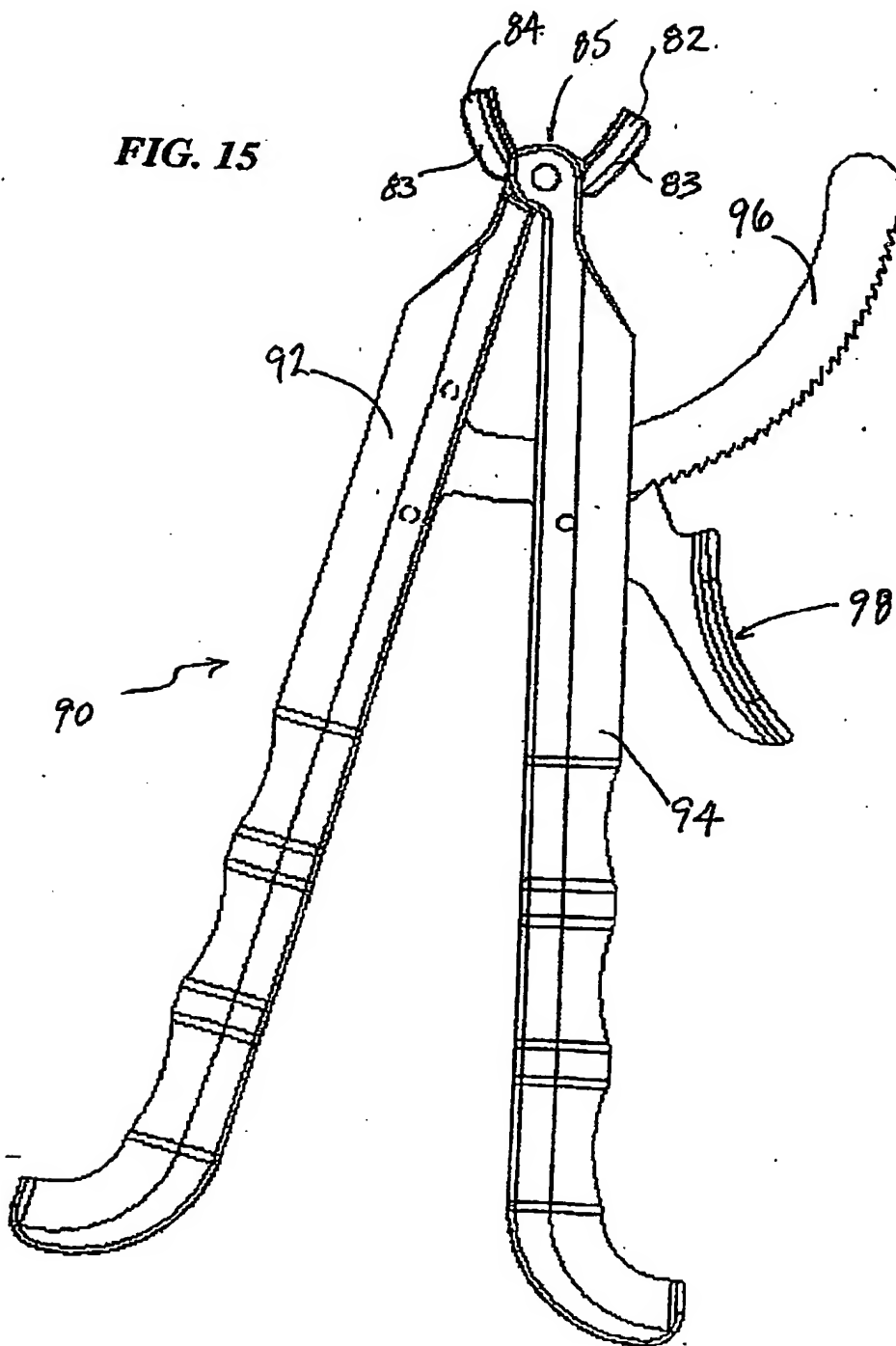
**FIG. 14**

FIG. 15



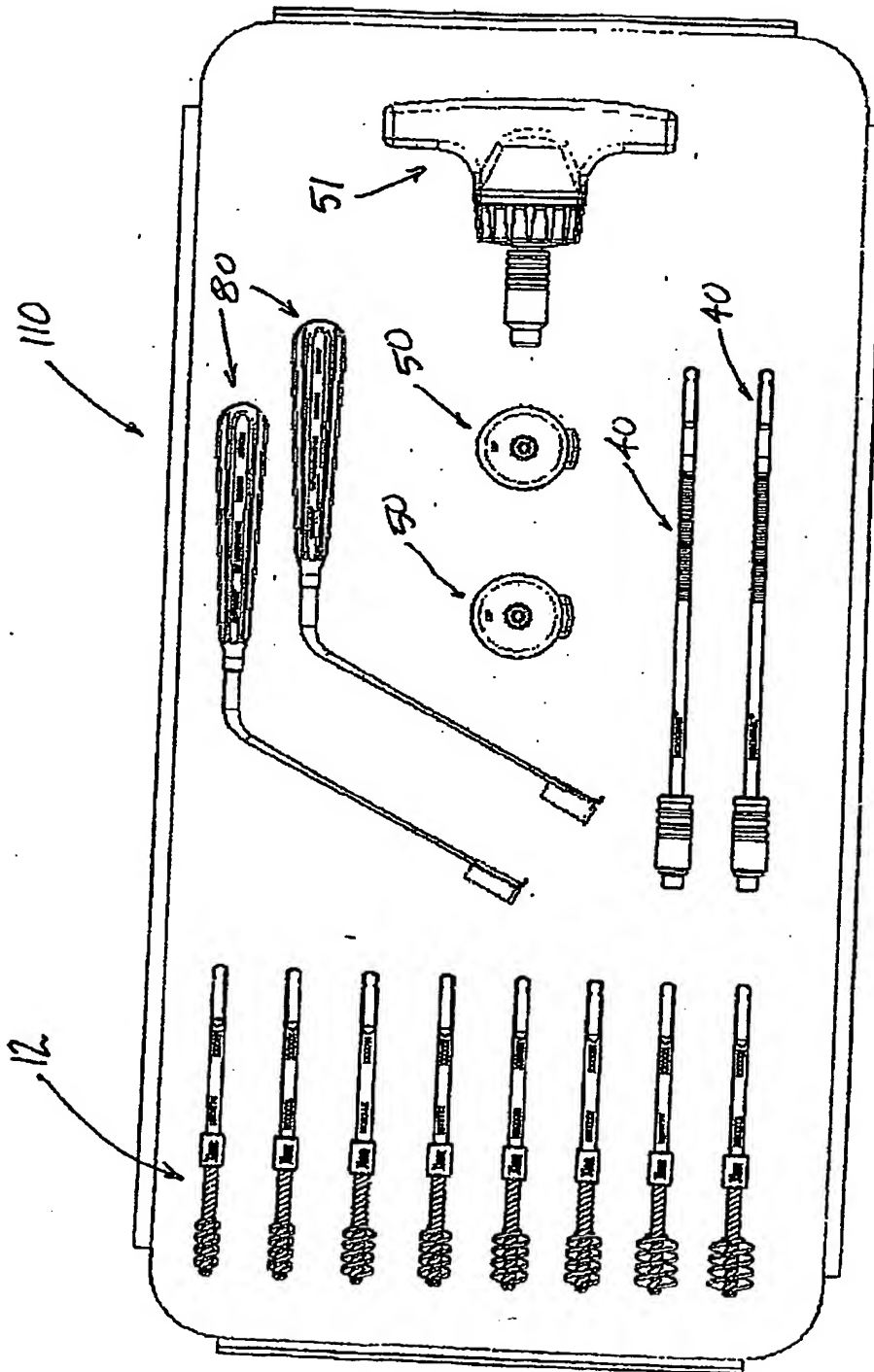


FIG. 16

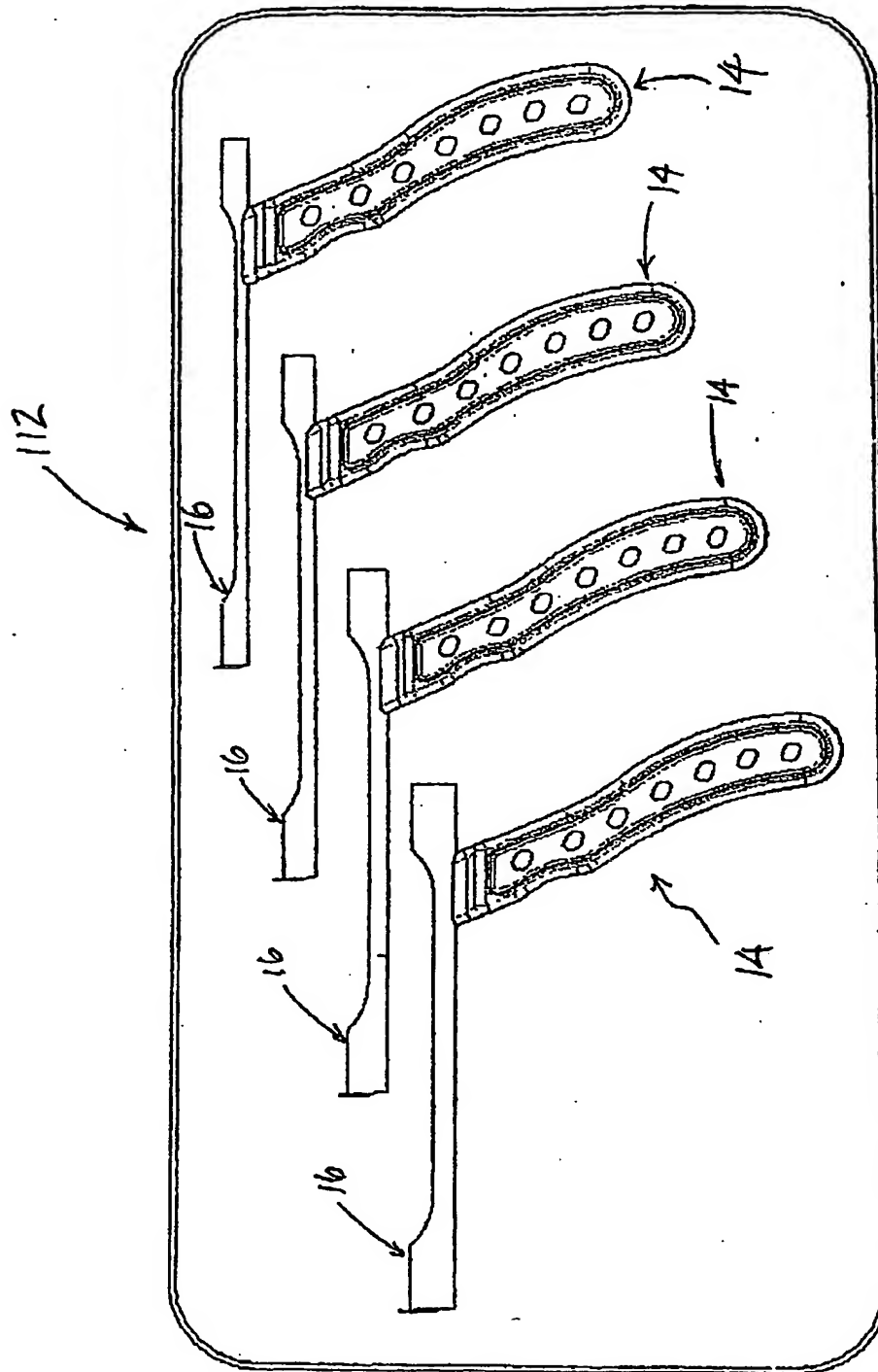


FIG. 17

FIG. 18

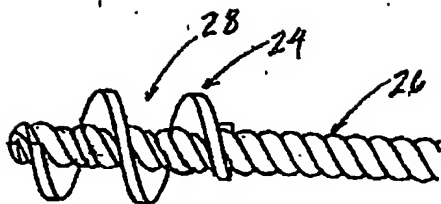


FIG. 19

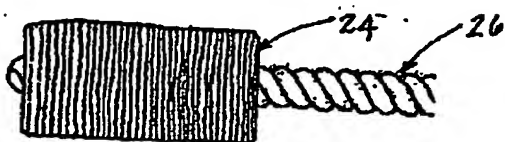


FIG. 20

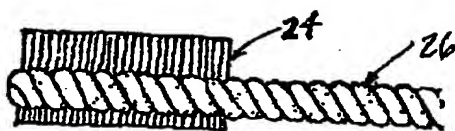


FIG. 21

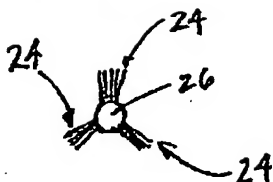


FIG. 22

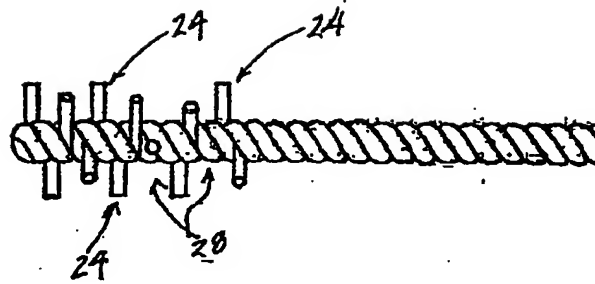


FIG. 23

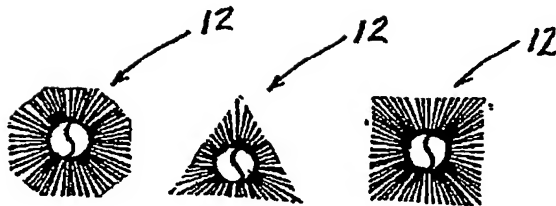
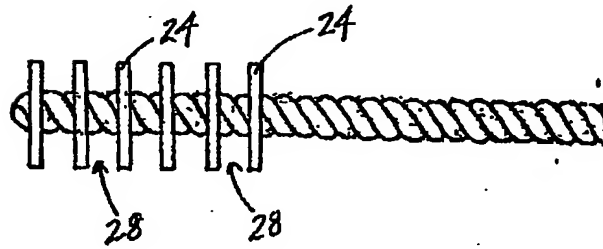


FIG. 24

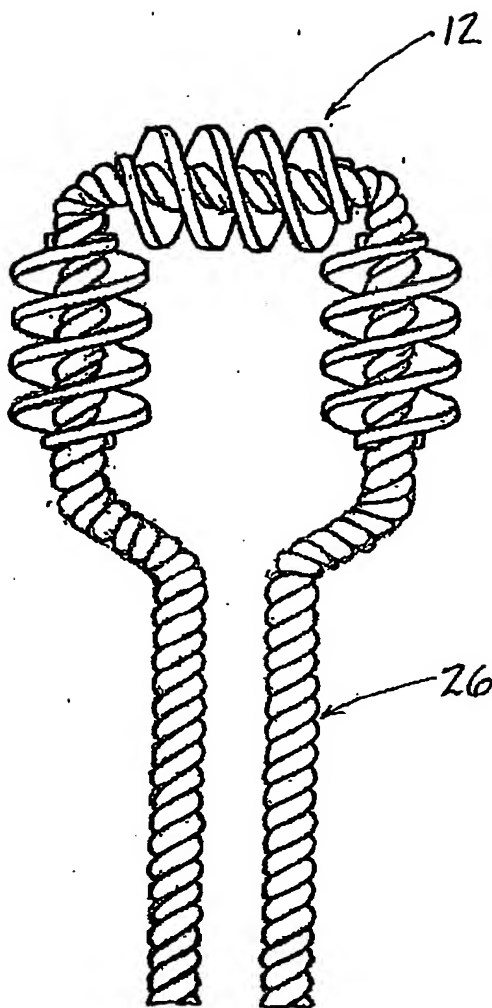


FIG. 25

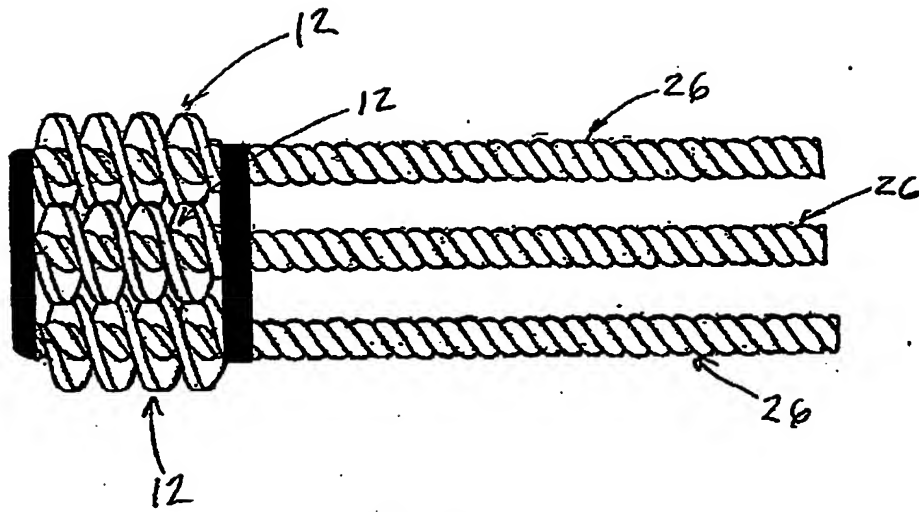


FIG. 26

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